

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
86683

MEDICAL REVIEW

REVIEW OF RESUBMISSION

DATE COMPLETED: 2-1-79

ANDA #: 86-683

CO. NAME: Purepac Pharm. Co.
Elizabeth, NJ 07207

APPROVAL DATE: none

NAME OF DRUG: Acetaminophen 300 mg. with Codeine Phosphate 60 mg. Tablets

DATE OF SUBMISSION: 1-25-79

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

1. Review of Studies: none submitted

2. Review of Labeling:

Container labels: none submitted.

Package insert: Satisfactory

CONCLUSION:

1. The firm should send in FPL of container labels identical in content to the draft copies submitted 9-18-79.
2. The package insert is acceptable.

RECOMMENDATIONS: The company is to be so notified.

/S/
J.R. Carr, D.D.S.

cc:dup
JRC/wlh/2-5-79

REVIEW OF ANDA

DATE COMPLETED: 10-10-78

ANDA #: 86-683

CO. NAME: Purepac Pharmaceutical Co.
Elizabeth, NJ 07207

F.R. DATE: 2-2-73

NAME OF DRUG: Acetaminophen 300 mg. with Codeine Phosphate 60 mg. Tablets

DATE OF SUBMISSION: 9-18-78

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Bioavailability requirement is deferred for this drug.

2. Review of Labeling:

Container labels: draft copies for containers of 100 and 1000 tablets --
satisfactory

Package insert: draft copy - needs revision

CONCLUSION:

1. The draft copies of the container labels are satisfactory
2. The draft copy of the package insert needs revision in accord with labeling guidelines.

RECOMMENDATIONS: The company is to be so notified and sent a copy of the labeling guidelines.

cc:dup

JRC/wlb/TG

/S/
J.N. Carr, D.D.S.